

Standard Operating Procedure External Audits and Inspections	
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Issued by: Director, Health Sciences Research	

1.0 POLICY

Health Canada (HC) has the authority to audit and/or inspect research sites conducting HC-approved clinical trials. The United States (US) Food and Drug Administration (FDA) and the European Medicines Agency (EMA) also have the authority to audit and/or inspect Canadian research sites conducting FDA/EMA-approved clinical trials.

Sponsors, contract research organizations (CROs), funding entities, research ethics boards (REB) and/or other bodies authorized by regulations and/or agreements with the research sites may also have the authority to audit and/or inspect research sites.

These audits and/or inspections may occur within the W.J. Henderson Centre for Patient Oriented Research (WJHCPOR); therefore, the WJHCPOR must have policies in place for dealing with internal/external audits and inspections.

This standard operating procedure (SOP) describes the correct procedures to be followed by all users of the WJHCPOR prior to, during, and following an internal/external audit or inspection. Audits and inspections can be carried out as routine or for cause.

2.0 PURPOSE

All users of the WJHCPOR must familiarize themselves with this SOP to ensure correct procedures are taken prior to, during and following an internal/external audit or inspection that involves the WJHCPOR. This SOP is applicable to all users who are conducting clinical research, including clinical trials, within the WJHCPOR.

3.0 DEFINITIONS

Audit – an examination, verification or review of all activities, documents, facilities, equipment, records, and other resources associated with clinical research, including clinical trials, to determine whether all research activities were conducted in compliance with the study protocol, site-specific and/or sponsor-specific SOPs, institutional and REB policies, good clinical practice (GCP), and other applicable regulatory requirements and guidelines. Audits are typically conducted to help ensure compliance with applicable standards, to correct errors before the research is completed, to identify low or high rate of adverse events when research sites are compared, and to verify the data is accurate and of quality.

Inspection – an official examination by regulatory authorities (i.e. HC or FDA) of all activities, documents, facilities, equipment, records, and other resources deemed by the regulatory authorities to be relevant and related to the clinical research, including clinical trials, to determine whether all research activities were conducted in compliance with the study protocol, site-specific and/or sponsor-specific SOPs, institutional and REB policies, good clinical practice (GCP), and other applicable regulatory requirements and guidelines. Inspection typically occurs at the research sites; however inspection can also occur at the sites of the Sponsor, CRO, funding entities, REB and/or other locations deemed appropriate by the regulatory authorities. Following an inspection, an official written report is provided that lists all observations, deviations, and deficiencies noted during the inspection.

4.0 RESPONSIBILITY

Users are responsible for:

- Notifying the designated KGHRI staff member of any planned internal/external audits or inspections of clinical research, including clinical trials, that will be, are being or have been conducted in the WJHCPOR.
- Notifying the dedicated KGHRI staff member if users will be booking space in the WJHCPOR for the Auditor(s) or Inspector(s) when on site for the audit or inspection.
- Notifying the dedicated KGHRI staff member whenever records will be requested that involve the WJHCPOR's facilities that were used by users for clinical research, including clinical trials, as part of the audit or inspection. Users will need to provide the dedicated KGHRI staff member with information regarding the specific records (i.e. equipment, SOPs, training logs) required and the time period when the research was conducted within the WJHCPOR in order for the appropriate documents to be made available for the audit or inspection.
- Notifying the dedicated KGHRI staff member if the Auditor(s) or Inspector(s) requires access to a printer within the WJHCPOR. A printer device code will be provided for each Auditor(s) or Inspector(s). Users will be responsible for all costs associated with printing related to the audit or inspection.

- Notifying the designated KGHRI staff member if he/she is required to meet with the Auditor(s) or Inspector(s). If possible and with permission of the Auditor(s) or Inspector(s), the designated KGHRI staff member should attend in person the “Opening Meeting”, “Final Closing Meeting”, and “Exit Meeting” of the audit or inspection. If possible and with permission of the Auditor(s) or Inspector(s), if additional meetings or discussions are to be held via teleconference with the Auditor(s) or Inspector(s), the designated KGHRI staff member should be notified and invited to attend.
- Ensuring that the Auditor(s) or Inspector(s) have signed KHSC’s Confidentiality Agreement, prior to the start of the audit or inspection. See KHSC Policy 11-150.
- Notifying KHSC’s Vice President of Health Sciences Research and KHSC’s Protection Services when Auditor(s) or Inspector(s) will be on site. All users must obtain a visitor pass for the Auditor(s) or Inspector(s) for all days on site. See KGH Policy 11-150.
- Providing KHSC, KGHRI, the WJHCPOR, and the dedicated KGHRI staff member with a copy of all draft and final written reports, including the “Draft Regulatory Exit Notice”, “Site/Sponsor Responses” to the written report, and the “Final Regulatory Exit Notice”.
 - KHSC, KGHRI, and the WJHCPOR, through the dedicated KGHRI staff member acting as a liaison, need to be allowed and given the opportunity to address any observations and findings noted during the audit or inspection that involve its facilities, including its equipment, furniture, space, people, and SOPs.
 - KHSC, KGHRI, the WJHCPOR, and the dedicated KGHRI staff member will help users to facilitate a response to these observations and findings and development of any intended corrective and preventative action (CAPA) plans, including projected timeframe for completion.
 - **PLEASE NOTE:** additional discussion(s) will be required with key stakeholders within KHSC, KGHRI, and Queen’s University prior to any final responses being provided to the Sponsor/CRO to pass along to the Auditor(s) or Inspector(s). KHSC, KGHRI, the WJHCPOR, and the dedicated KGHRI staff member will work with the key stakeholders to develop the responses after discussion(s) have occurred. KHSC, KGHRI, and Queen’s University **MUST** sign off on all responses prior to dissemination. It is important that users notify the dedicated KGHRI staff member as soon as possible to meet any deadlines imposed by the Auditor(s) or Inspector(s).
 - KHSC, KGHRI, the WJHCPOR, or the dedicated KGHRI staff member will notify the Sponsor/CRO and users if additional time is required to develop responses to the observations and findings and development of any CAPA plans, including projected timeframe for completion. It is the Sponsor’s/CRO’s responsibility to reach out to the Auditor(s) or Inspector(s) to request an extension to any deadlines imposed by the Auditor(s) or Inspector(s).

KGHRI is responsible for:

- Ensuring access to the appropriate records and documents (i.e. calibration records, temperature logs, training logs, associated SOPs) for the Auditor(s) or Inspector(s).
- Providing a printer device code to the users for the Auditor(s) or Inspector(s) to use for photocopying during the audit or inspection.
- Ensuring that the dedicated KGHRI staff member is available to meet with the Auditor(s) or Inspector(s) to provide any clarifications and/or answer any of their questions or queries related to the WJHCPOR’s facilities, including its equipment, furniture, space, people, and SOPs, if required.
- Ensuring that the dedicated KGHRI staff member is available to attend the “Opening Meeting”, “Final Closing Meeting”, and “Exit Meeting” and any other meeting(s) or discussion(s) with the Auditor(s) or Inspector(s), if permission is granted.
- Assisting the Sponsor/CRO with providing a written response to the Auditor(s) or Inspector(s), in consultation with our university and hospital partners, to all observations and findings noted in written reports including the development of any CAPA plans and projected timeframe for completion related to the WJHCPOR’s facilities, including its equipment, furniture, space, people, and SOPs.
- Notifying the Sponsor/CRO and users if additional time is required to develop responses to the observations and findings, including development of any CAPA plans and projected timeframe for completion related to the WJHCPOR’s facilities, including its equipment, furniture, space, people, and SOPs.

5.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-EAI-01	01-MAY-2019	Original version.